AUG 11 2004

K041697

Terumo Circuit Connectors

Submitter Information:

This submission was prepared in June 2004 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
28 Howe Street
Ashland, MA 01721

Device Names:

Proprietary Name:	Terumo Circuit Connectors
Classification Name:	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Common Name:	Circuit Connectors

Device Classification:

The Terumo Circuit Connectors are classified as: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass – in the *Code of Federal Regulations*, 21, Parts 800 to 1299, § 870.4290.

Predicate Device:

The devices submitted in this 510(k) maintain characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following devices:

Proposed Device	*Predicate Device*
0007-04439 - U-Tube Connector	Brevet Connector (K895753)
0007-02118 - 3/16 Male Slip Connector	Brevet Connector (K895753) – P/N 118
0007-03056 - 1/ 4" Quick Disconnect	Brevet Connector (K895753) – P/N 100
0007-04056 - 3/8" Quick Disconnect	Brevet Connector (K895753) – P/N 101
0007-05056 - 1/2" Quick Disconnect	Brevet Connector (K895753) – P/N 102

Intended Use:
The Terumo Circuit Connectors are intended to be used to interconnect tubing and other devices within a circuit during extra-corporeal bypass procedures. The devices can be used in procedures lasting up to 6 hours in duration.

Principles of Operation and Technology:
The connectors that are the subject of this premarket notification perform by providing a connection between devices within a bypass circuit, effectively establishing a conduit between the devices for the flow of blood and other extra-corporeal fluids.

Design and Materials:
The connectors that are the subject of this premarket notification are of various designs (quick disconnect, slip connection, etc.), each of which provides for the flow of blood and extra-corporeal fluids through the bypass circuit. Each of the connectors is made from various plastics – all of which are common in medical devices that are already on the market. There are no new and/or exotic materials used in the manufacturing of the proposed devices.

Performance Evaluations:
Clinical studies are not necessary to demonstrate safety or substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- 6-Hour Circulation Test - (Comparative v. predicate devices)
- Dimensional Analysis - (Attribute Evaluation / Not compared to predicate)
- Structural Integrity / Leakage Testing - (Attribute Evaluation / Not compared to predicate)
- Tubing Connection Strength - (Attribute Evaluation / Not compared to predicate)

Substantial Equivalence Comparison:
The Terumo Circuit Connectors are substantially equivalent to the predicate Brevet Connector devices as follows:

- *Intended Use*: The intended uses of the Terumo Connectors and the predicate Brevet Connectors are essentially the same. The devices are intended to interconnect tubing and other devices within a circuit during extra-corporeal bypass procedures. The devices can be used in procedures lasting up to 6 hours in duration.

- *Principles of Operation and Technology*: The technology of the Terumo Connectors and the predicate Brevet Connectors are identical. The devices operate by providing a mechanical connection between and among the devices that comprise the extra-corporeal circuit. When the connectors are sufficiently placed into position, they provide the necessary interface between circuit components to establish a conduit for the flow of fluids.

- *Design and Materials*: The design and the materials of the Terumo Connectors and the predicate Brevet Connectors are essentially the same. The design of each device is similar in that each is manufactured of hardened plastic – and contains the necessary interface to allow for the interconnection of other devices.

- *Performance*: Comparisons of the performance of the Terumo Connectors and the predicate Brevet Connectors were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the devices.

Substantial Equivalence Summary:
In summary, the Terumo Connectors and the predicate Brevet Connectors (K895753) are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject devices and the predicate devices do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated in accordance with appropriate guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed the maximum residue limits at the time of product distribution.

- Terumo conducted biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

Conclusion:
In summary, the Terumo Circuit Connectors are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate Brevet Connectors (K895753).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2004

Mr. Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K041697
Trade Name: Terumo Circuit Connectors
Regulation Number: 21 CFR 870.4290
Regulation Name: Circuit Connectors
Regulatory Class: Class II (two)
Product Code: DTL
Dated: June 18, 2004
Received: June 22, 2004

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K041697

Device Name: **Terumo Circuit Connectors**

Indications For Use:

The Terumo Circuit Connectors are intended to be used to interconnect tubing and other devices within a circuit during extra-corporeal bypass procedures. The devices can be used in procedures lasting up to 6 hours in duration.

Garry A. Courtney, MBA, RAC
Sr. Regulatory Affairs Specialist
Terumo Cardiovascular Systems

Prescription Use X AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041697